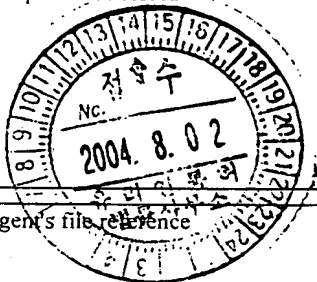


PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING

To:
KONG, Seok-Kyun

#202 Seohan Building, 943-2 Dogok-Dong, Gangnam-Gu,
Seoul 135-270, Republic of Korea



PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing
(day/month/year) 26 JULY 2004 (26.07.2004)

Applicant's or agent's file reference
2003PCT27

REPLY DUE within 1 months from
the above date of mailing

International application No.

PCT/KR2003/002280

International filing date (day/month/year)

27 OCTOBER 2003 (27.10.2003)

Priority date(day/month/year)

29 OCTOBER 2002 (29.10.2002)

International Patent Classification (IPC) or both national classification and IPC

IPC7 A61K 31/4375, A61P 25/30

Applicant

SUNGKYUNKWAN UNIVERSITY et al

1. This written opinion is the first (first,etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When ? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d)


How ? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3
For the form and the language of the amendments, see Rules 66.8 and 66.9

Also For an additional opportunity to submit amendments, see Rule 66.4
For an examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 18 FEBRUARY 2005 (18.02.2005)

Name and mailing address of the IPEA/KR

 Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon 302-701,
Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

LEE, HYUN SONG

Telephone No. 82-42-481-5606



WRITTEN OPINION

International application No.

PCT/KR2003/002280

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement) under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

- These elements were available or furnished to this Authority in the following language English which is
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheet/fig _____

5.

- ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International application No.

PCT/KR2003/002280

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	3-4	YES
	Claims	1-2	NO
Inventive step (IS)	Claims		YES
	Claims	3-4	NO
Industrial applicability (IA)	Claims	1-4	YES
	Claims		NO

2. Citations and explanations

D1: A. BRISSEMORET, 'Note Sur Les Plantes Anti-Opium', Comptes Rendus des Seances de la Societe de Biologie et de Ses Filiales, 1925, Vol. 93, 1341-1343.

D2: GE XIAOQUN, ZHANG HONGQUAN, ZHOU HAUZHU, XU ZHENGXIN, BIAN CHUNFU, 'Experimental Study of Tetrahydroprotoberberines Inhibiting Morphine Withdrawal Syndromes', Chin. J. Drug Depend.(Zhongguo Yaowu Yilaixing Zazhi), 1999, Vol. 8, No. 3, 195-198.

본원 발명은 정신적 의존성 및 자발운동의 증가에 대하여 억제효과를 나타내는 베르베린을 함유하는 오피류 중독 치료 또는 예방용 약제(제1항, 제2항), 베르베린을 유효성분으로 함유하는 오피류 작용 내성 형성 예방 및 억제용 약제(제3항, 제4항)를 발명의 요지로 하는 것이며,

D1에는 베르베린이 오피와 헤로인의 중독 치료에 효과가 있음이 기재되어 있으며, D2에는 테트라하이드로베르베린이 오피에 중독된 쥐의 금단증상을 억제하는데 효과가 있음이 기재되어 있는 바,

1) 신규성

본원의 제1항 및 제2항의 베르베린의 중독 치료 또는 예방용 약제는 D1의 베르베린이 오피의 중독 치료에 효과가 있는 점과 동일한 것으로 인정되며,

D1 및 D2에 베르베린을 이용하여 오피류 진통제의 작용 내성 형성 예방 및 억제에 대한 효과가 직접적으로 기재되어 있지 않는 바, 본원 제3항 및 제4항은 신규한 것으로 인정되며.(Article 33(2) PCT)

2) 진보성

오피와 같은 마약성 진통제는 반복적으로 장기간 사용하는 경우에 진통 작용에 대한 내성이 생기며, 습관성과 탐닉성이 생기는 것은 본원에서 언급한 바와 같이 공지의 사실인 바, 오피의 중독치료에 사용되는 베르베린을 진통작용에 대한 내성 형성을 예방하거나 억제하는 약제로 사용하는데 각별한 곤란성이 인정되지 않고, 그로 인한 효과 또한 당업자가 용이하게 예측할 수 있는 것으로 인정되는 바, 본원 제3항 및 제4항은 진보하지 않는 것으로 인정되고.(Article 33(3) PCT)

3) 산업상 이용가능성

본원 발명은 베르베린을 함유하는 약제로서 산업상 이용 가능한 것으로 인정됩니다.(Article 33(4) PCT)